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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	CURTISS III et al
Serial No.:	10/620,777
Filed:	July 15, 2003
Entitled:	RECOMBINANT BACTERIAL SYSTEM WITH ENVIRONMENTALLY LIMITED VIABILITY

Art Unit: 1645

Examiner:

Attorney Docket No.: MEG-207.1 US-1

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Transmitted herewith are: [X] an Information Disclosure Statement (8 pages), with a modified Form 1449 (6 pages); [X] a return receipt postcard, to be filed in the above-identified patent application.

FEE FOR ADDITIONAL CLAIMS

- [X] A fee for additional claims is not required.
[] A fee for additional claims is required. The additional fee has been calculated as shown below:

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	NUMBER OF EXCESS CLAIMS	RATE	FEES DUE
TOTAL CLAIMS	--	--	0	\$50	= 0.00
INDEPENDENT	--	--	0	\$200	= 0.00
FIRST INTRODUCTION OF MULT. DEPENDENT CLAIM				\$360	= 0.00
TOTAL FEES DUE					= 00.00

PAYMENT OF ADDITIONAL FEES

- [] A check in the amount of \$____ in payment of the fee for additional claims is transmitted herewith.
[] Please charge \$____ to Deposit Account No. 50-0268 in payment of the fee for additional claims.
A duplicate copy of this transmittal letter is transmitted herewith.

- ☐ A check including the amount of \$___ in payment of the fee for the submission of an Information Disclosure Statement is transmitted herewith.
- ☒ The Commissioner is hereby authorized to charge payment of any additional fees required under 37 CFR 1.16 or 1.17 in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to Deposit Account No. 50-0268. A duplicate copy of this transmittal letter is transmitted herewith.

PETITION FOR EXTENSION OF TIME

- ☐ Extension is requested under 37 CFR 1.136(a), and the following extension fee is applicable for the Response filed herewith: ☐ \$120.00 for response within first month pursuant to 37 CFR 1.17(a)(1);
☐ \$450.00 for response within second month pursuant to 37 CFR 1.17(a)(2);
☐ \$1,020.00 for response within third month pursuant to 37 CFR 1.17(a)(3);
☐ \$1590.00 for response within fourth month pursuant to 37 CFR 1.17(a)(4);
☐ \$2160.00 for response within fifth month pursuant to 37 CFR 1.17(a)(5).
- ☐ A check including the amount of ☐ \$120.00 ☐ \$450.00 ☐ \$1,020.00 ☐ \$1590.00 ☐ \$2160.00 in payment of the extension fee is transmitted herewith.
- ☒ The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to Deposit Account No. 50-0268. A duplicate of this transmittal letter is submitted herewith.

Respectfully submitted,



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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below:

January 28, 2005

Date



Nasim G. Memon



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**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Dear Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 C.F.R. §§ 1.97 and 1.98 in the above-identified application for consideration by the Patent Office. This application is a Continuation of U.S. patent application Serial Number 08/761,769 filed on December 6, 1996. The '769 patent application is a Continuation In Part of patent application 08/473,789 filed on June 7, 1995.

A modified Form PTO-1449 listing the cited documents is also enclosed. Copies of all these cited references have been provided to the USPTO in the above-mentioned patent applications. This Statement is being submitted before the first Office Action on the merits. Pursuant to 37 C.F.R. § 1.97(b)(3), no fee is believed to be required with this submission.

US Patents

US 4,190,495; issued February 26, 1980, Curtiss;
US 4,968,619; issued November 6, 1990, Curtiss;
US 5,190,931; issued March 2, 1993, Inouye;
US 5,681,745; issued October 28, 1997, Szafranski et al; and
US 5,702,916; issued December 30, 1997, Molin, et al.

Foreign Patent Documents:

EP 0381706 B1 published April 26, 1995, Curtiss.

Other Documents – Non-Patent Literature – Publications:

Barrett, Textbook of Immunology, Fourth Edition, (C. V. Mosby Co., St. Louis, MO, 1983)

Bienkowska-Szewczyk et al., "The R Gene Product of Bacteriophage λ ", Mol. Gen Genet., 184:111-114 (1981)

Bochner et al., "Positive Selection for Loss of Tetracycline Resistance", J. Bacteriol., 143:926 (1980)

Brosius, "Plasmid Vectors for the Selection of Promoters", Gene, 27:151-160 (1984)

Cardenas and Clements, "Oral Immunization Using Live Attenuated *Salmonella* spp. as Carriers of Foreign Antigens", Clinical Micro. Rev., 5(3) :328-342 (1992)

Cardineau and Curtiss, "Nucleotide Sequence of the *asd* Gene of *Streptococcus mutans*", J. Bio. Chem., 262:3344-3353 (1987)

Chatfield et al., "Construction of a Genetically Defined *Salmonella typhi* Mutant for the Engineering of a Candidate Oral Typhoid-Tetanus Vaccine", Vaccine, 10:53-60 (1992)

Chatfield et al., "The Development of Oral Vaccines Based on Live Attenuated *Salmonella* Strains", FEMS Immunol. Med. Microbiol., 7:1-7 (1993)

Christie, et al., "Synthetic Sites for Transcription Termination and a Functional Comparison with Tryptophan Operon Termination Sites In Vitro", Proc. Natl. Acad. Sci. USA, 78:4180-4184 (1981)

Clements, "Use of Attenuated Mutants of *Salmonella* as Carriers for Delivery of Heterologous Antigens to the Secretory Immune System", Pathol. Immunopathol. Res., 6:137-146 (1987)

Cornelis, "Yersiniae, Finely Tuned Pathogens", Molecular Biology of Bacterial Infections (Cambridge University Press, Cambridge, 1992)

Curtiss, III. "The Release of Genetically-Engineered Microorganisms", Proceedings of the First International Conference on the Release of Genetically-Engineered Microorganisms (Sussman et al. editors, Academic Press 1988), pp. 7-19

Curtiss, "Genetic Manipulation of Microorganisms: Potential Benefits and Biohazards", Ann. Rev., 30:507-533 (1976)

Curtiss et al., "Research on Bacterial Conjugation with Mini-Cells and Minicell-Producing *E. Coli* Strains", Microbial Drug Resistance, 3:169-183 (1982)

Curtiss and Kelly, "*Salmonella Typhimurium* Deletion Mutants Lacking Adenylate Cyclase and Cyclic AMP Receptor Protein are Avirulent and Immunogenic", Infect. Imm., 55:3035-3043 (1987)

Curtiss et al., "Chromosomal Aberrations associated with Mutations to Bacteriophage Resistance in Escherichia Coli", J. Bacteriol., 89:28-40 (1965)

Curtiss et al., "Avirulent Salmonella Expressing Virulence Antigens from other Pathogens for Use as Orally Administered Vaccines", Virulence Mechanisms Of Bacterial Pathogens (Roth, American Society for Microbiology, Washington, D.C., 1988) pages 311-328

Curtiss et al., "Recombinant Salmonella Vectors in Vaccine Development", Dev. Biol. Stand., 82:23-33 (1994)

Curtiss et al., "Stable Recombinant Avirulent Salmonella Vaccine Strains", Adv. E. Med. Biol., 251:33-47 (1989)

Curtiss et al., "Selective Delivery of Antigens by Recombinant Bacteria", Curr. Topics Micro. Immun., 46:35-49 (1989)

Curtiss, "Attenuated Salmonella Strains as Live Vectors for the Expression of Foreign Antigens", New Generation Vaccines (Woodrow and Levine, eds., Marcel Dekker, New York, 1990) pages 161-188

Doggett and Curtiss, "Delivery of Antigens by Recombinant Avirulent Salmonella Strains", Adv. Exp. Med. Biol., 327:165-73 (1992)

Dorman et al., "Characterization of Porin and ompR Mutants of a Virulent Strain of Salmonella typhimurium: ompR Mutants are Attenuated In Vivo", Infect. Immun., 57:2136-40 (1989)

Dougan et al., "Live Oral Salmonella Vaccines: Potential Use of Attenuated Strains as Carriers of Heterologous Antigens to the Immune System", Parasite Immun., 9:151-160 (1987)

Dul et al., "Genetic Mapping of a Mutant Defective in D, L-Alanine Racemase in Bacillus Subtilis 168", J. Bacteriol., 115:1212 (1973)

Ferrari et al., "Isolation of an Alanine Racemase Gene from Bacillus Subtilis and its Use for Plasmid Maintenance in B. Subtilis", Bio/Technology, 3:1003-1007 (1985)

Gait, ed., "Oligonucleotide Synthesis", A Practical Approach, (1984)

Galan and Curtiss, "Virulence and Vaccine Potential of phoP Mutants of Salmonella typhimurium", Microb. Pathogen., 6:433-443 (1989)

Galan et al., "Cloning and Characterization of the asd gene of Salmonella typhimurium: Use in Stable Maintenance of Recombinant Plasmids in Salmonella Vaccine Strains", Gene, 94(1):29-35 (1990)

Gentschev et al., "Salmonella Strain Secreting Active Listeriolysin Changes its Intracellular Localization", Infect. Imm., 63:4202-4205 (1995)

Gerdes et al., "Mechanism of Postsegregational Killing by the hok Gene Product of the parB System Of Plasmid R1 and its Homology with the relF Gene Product of the E. coli relB Operon", EMBO J., 5:2023-2029 (1986)

- Gerdes et al., "The hok Killer Gene Family in Gram-Negative Bacteria", New Biol., 2:946-956 (1990)
- Gerdes et al., "Unique Type of Plasmid Maintenance Function: Postsegregational Killing of Plasmid-Free Cells", Proc. Nat'l Acad. Sci. USA, 83:3116-3120 (1986)
- Germanier and Furer, "Immunity in Experimental Salmonellosis", Infect. Immun., 4:663-73 (1971)
- Germanier and Purer, "Isolation and Characterization of Gal E Mutant Ty 21a of Salmonella typhi: A Candidate Strain for a live, oral Typhoid vaccine", J. Infect. Dis., 131:553-8 (1975)
- Giladi et al., "Integration Host Factor Stimulates the Phage Lambda pL Promoter", J. Mol. Biol., 231:109-121 (1990)
- Givskov et al., "Cloning and Expression in Escherichia coli of the Gene for extracellular Phospholipase A1 from Serratia liquefaciens", J. Bacteriol., 170:5855-5862 (1988)
- Glover, ed., "DNA Cloning", A Practical Approach, Volumes I and II (1985)
- Guzman et al., "Tight Regulation, Modulation, and High-Level Expression by Vectors containing the Arabinose PBAD Promoter", J. Bacteriol., 177(14):4121-4130 (1995)
- Hames and Higgins, eds., "Nucleic Acid Hybridization", A Practical Approach (1984)
- Hecker et al., "Role of relA Mutation in the Survival of Amino Acid-Starved Escherichia coli", Arch. Microbiol., 143:400-402 (1986)
- Helander et al., "Preferential Synthesis of Heptaacyl Lipopolysaccharide by the ssc Permeability Mutant Of Salmonella typhimurium", Eur. J. Biochem., 204:1101-1106 (1992)
- Hess et al., "Superior efficacy of secreted over Somatic Antigen display in Recombinant Salmonella Vaccine induced Protection against Listeriosis", Proc. Natl. Acad. Sci. USA, 93:1458-1463 (1996)
- Hirvas et al., "Identification and Sequence Analysis of the Gene Mutated in the Conditionally Lethal Outer Membrane Permeability Mutant SS-C Of Salmonella typhimurium", EMBO J., 10(4):1017-1023 (1991)
- Hoe et al., "Temperature Sensing in Yersinia pestis: Regulation of yopE Transcription by lcrF", J. Bacteriol., 174:4275-4286 (1992)
- Hone et al., "A galE via (Vi Antigen-Negative) Mutant of Salmonella typhi Ty2 retains Virulence in Humans", Infect. Immun., 56:1326-1333 (1988)
- Hromockyi et al., "Temperature Regulation of Shigella Virulence: Identification of the Repressor Gene virR, An Analogue of hns, and Partial Complementation by Tyrosyl transfer RNA (tRNA^{Tyr})", Mol. Micro., 6:2113-2124 (1991)
- Jaguszyn-Krynicka et al., "Expression of Streptococcus mutans Aspartate-Semialdehyde Dehydrogenase gene cloned into plasmid pBR322", J. Gen. Microbiol., 128:1135-1145 (1982)
- Johnson et al., "The Role of s Stress-Response Protein in Salmonella typhimurium Virulence", Mol. Microbiol., 5:401-407 (1991)

Jones et al., "Induction Of Proteins In Response To Low Temperature In Escherichia coli", J. Bacteriol., 169:2092-2095 (1987)

Kaniga et al., "A Wide-Host Suicide Vector For Improving Reverse Genetics In Gram-Negative Bacteria: Inactivation Of The blaA Gene Of Yersinia enterocolitica", Gene, 109:137-141 (1991)

Kelly et al., "Characterization And Protective Properties Of Attenuated Mutants Of Salmonella choleraesuis", Infect. Immun., 60:4881-4890 (1992)

Kingsbury et al., "Temperature-Sensitive Mutants for the Replication of Plasmids in Escherichia coli: Requirement for Deoxyribonucleic Acid Polymerase I in the Replication of the Plasmid CoIE1", J. Bacteriol., 114:1116-1124 (1973)

Knudsen and Karlstrom, "Development of Efficient Suicide Mechanisms for Biological Containment of Bacteria", Applied and Environmental Microbiology, 57(1) :85-92 (1991)

Kushner, "Construction of Versatile Low-Copy-Number Vectors for Cloning, Sequencing and Gene Expression in Escherichia coli", Gene, 100:195-199 (1990)

Lambert de Rouvroit et al., "Role of the Transcriptional Activator, VirF, and Temperature in the Expression of the pYV Plasmid Genes of Yersinia enterocolitica", Molec. Microbiol., 6:395-409 (1992)

Lieb, "Studies of Heat-Inducible Lambda Bacteriophage", J. Mol. Biol., 16:149-163 (1966)

Lugtenberg et al., "Temperature-Sensitive Mutant of Escherichia coli K-12 with an Impaired D-Alanine: D-Alanine Ligase", J. Bacteriol., 113:96-104 (1973)

McGhee and Mestecky, "The Secretory Immune System", Ann. N.Y. Acad. Sci., Volume 409 (1983)

Miller, Experiments In Molecular Genetics (Cold Spring Harbor Laboratory, 1972)

Miller et al., "A Two-Component Regulatory System (phoP phoQ) controls Salmonella typhimurium virulence", Proc. Natl. Acad. Sci. USA, 86:5054-5058 (1989)

Miller and Mekalanos, "A Novel Suicide Vector and its Use in Construction of Insertion Mutations: Osmoregulation of Outer Membrane Proteins and Virulence Determinants in Vibrio cholerae requires toxR", J. Bacteriol., 170:2575-2583 (1988)

Miller, A Short Course In Bacterial Genetics (Cold Spring Harbor Laboratory, 1992)

Miyakawa et al., "Cell Wall Peptidoglycan Mutants of Escherichia coli K-12: Existence of Two Clusters of Genes, mra and mrb, For Cell Wall Peptidoglycan Biosynthesis", J. Bacteriol., 112:950 (1972)

Molin et al., "Suicidal Genetic Elements and their Use in Biological Containment of Bacteria", Annual Review of Microbiology, 47:139-166 (1993)

Molin and Kjelleberg, "Release of Engineered Microorganisms: Biological Containment and Improved Predictability for Risk Assessment", AMBIO, 22{4} :242-245 (1993)

Molin et al., "Conditional Suicide System for Containment of Bacteria and Plasmids", Bio/Technology, 5:1315-1318 (1987)

Munthali et al., "Use of Colicin E3 for Biological Containment of Microorganisms", App. Environ. Microbiol., 62(5):1805-1807 (1996)

Nakayama et al., "Construction of an ASD+ Expression-Cloning Vector: Stable Maintenance and High Level Expression of Cloned Genes in a Salmonella Vaccine Strain", Bio/Technology, 6:693-697 (1988)

Neidhardt et al., "The Genetics and Regulation of Heat-Shock Proteins", Annu. Rev. Genet., 18:295-329 (1984)

Nystrom, "Role Of Guanosine Tetraphosphate in Gene Expression and the Survival of Glucose or Seryl-tRNA Starved Cells of Escherichia coli K12", Mol. Gen. Genet., 245:355-362 (1994)

O'Brien, ed., Genetic Maps (Cold Spring Harbor Laboratory, 1987)

O'Connor and Timmis, "Highly Repressible Expression System for Cloning Genes that Specify Potentially Toxic Proteins", J. Bacteriol., 169:4457-4462 (1987)

Orga et al., Handbook of Mucosal Immunology (Academic Press, San Diego, CA, 1994)

Perbal, A Practical Guide To Molecular Cloning, A Wiley- Interscience Publication (1984)

Poteete et al., "Operator Sequences of Bacteriophages P22 And 21", J. Mol. Biol., 137:81-91 (1980)

Poulsen et al., "The *gef* Gene from Escherichia coli is Regulated at the Level of Translation", Mol. Microbiol., 5:1639-1648 (1991)

Qoronfleh et al.; "Identification and Characterization of Novel Low-Temperature-Inducible Promoters of Escherichia coli", J. Bacteriol., 174:7902-7909 (1992)

Ramos et al., "Suicide Microbes on the Loose", Bio/Technology, 13:35-37 (1995)

Reader and Siminovitch, "Lysis Defective Mutants of Bacteriophage Lambda: On the Role of the S Function in Lysis1", Virology, 43:623-637 (1971)

Reddy, et al., "Hyperexpression and Purification of Escherichia Coli Adenylate Cyclase Using a Vector Designed for Expression of Lethal Gene Products", Nucleic Acids Res., 17(24):10473-10489 (1989)

Remaut, et al., "Plasmid Vectors for High-Efficiency Expression controlled by the pL Promoter of Coliphage Lambda", Gene, 15:81-93 (1981)

Remaut, et al., "Improved Plasmid Vectors with a Thermoinducible Expression and Temperature-Regulated Runaway Replication", Gene, 22:103-113 (1983)

Rennell and Poteete, "Phage P22 Lysis Genes: Nucleotide Sequences and Functional Relationships with T4 and λ Genes", Virology, 143:280-289 (1985)

- Rodriguez and Denhardt, eds., Vectors: A Survey Of Molecular Cloning Vectors And Their Uses (Butterworths, 1987)
- Sambrook et al., Molecular Cloning: A Laboratory Manual (Cold Spring Harbor Laboratory, 1989)
- Sanger et al., "Nucleotide Sequence of Bacteriophage λ DNA", J. Mol. Biol., 162:729-773 (1982)
- Sauer et al., "Primary Structure of the Phage P22 Repressor and its Gene c2", Biochem., 20:3591-3598 (1981)
- Schadel, "Oral Vaccination using Recombinant Bacteria", Semin. Immunol., 2:341-349 (1990)
- Schadel, "Recombinant Avirulent Salmonellae as Oral Vaccine Carriers", Infection, 20(1):1-8 (1992)
- Schweder et al., "Escherichia coli K12 relA Strains as safe Hosts for Expression of Recombinant DNA", Appl. Microbiol. Biotechnol., 42:718-723 (1995)
- Sigwart et al., "Effect of a purA Mutation on Efficacy of Salmonella Live-Vaccine Vectors", Infection and Immunity, 57(6) :1858-1861 (1989)
- Sites et al., Basic and Clinical Immunology (Lange Medical Books, Los Altos, CA, 1994)
- Sizemore et al., "Attenuated Shigella as a DNA Delivery Vehicle for DNA-Mediated Immunization", Science, 270:299-302 (1995)
- Spector and Cubitt, "Starvation-Inducible Ioci of Salmonella typhimurium: Regulation and Roles in Starvation-Survival", Mol. Micro., 6:1467-1476 (1992)
- Studier et al., "Gene Expression Technology", Methods Enzymol., 185:60-89 (1990)
- Tacket et al., "Comparison of the Safety and Immunogenicity of AcpA ACrp Salmonella typhi Strains in Adult Volunteers", Infect. Immun., 60:536-541 (1992)
- Tanabe et al., "Identification of the Promoter Region of the Escherichia coli Major Cold Shock Gene, cspA", J. Bacteriol. 174:3867-3873 (1992)
- Tao and Blumenthal, "Sequence and Characterization of pvuIIR, The PvuII Endonuclease Gene, and of puvIIC, Its Regulatory Gene", J. Bacteriol., 174(10) :3395-3398 (1992)
- Temple et al., "Survival of two Enterobacteria in feces buried in soil under field conditions", Appl. Environ. Microbiol., 40:794-797 (1980)
- Tobe et al., "Temperature-Regulated Expression of Invasion Genes in Shigella Flexneri is Controlled through the Transcriptional Activation of the virB Gene on the large Plasmid", Mol. Micro. 5:887-893 (1991)
- Umbarger, "Amino Acid Biosynthesis and its Regulation", Ann. Rev. Biochem., 47:533 (1978)
- Vasina and Baneyx, "Recombinant Protein Expression at Low Temperatures under the Transcriptional

Control of the Major Escherichia coli Cold Shock Promoter cspA", Appl. Environ. Micro., 62(4) :1444-1447 (1996)

Vuorio and Vaara, "Mutants carrying conditionally lethal Mutations in Outer Membrane Genes omsA And lirA (ssc) are Phenotypically similar, and omsA is Allelic to firA", J. Bacteriol., 174(22) :7090-7097 (1992)

Wijsman, "The characterization of an Alanine Racemase mutant of Escherichia coli", Genet. Res. Camb., 20:269-277 (1972)

Wijsman, "A Genetic Map of several mutations affecting the Mucopeptide layer of Escherichia coli", Genet. Res. Camb., 20:65- 74 (1972)

Yarrington et al., "Dual-Origin Plasmid Vectors whose Origin of Replication is Controlled by the Coliphage Lambda Promoters PL" Gene, 28:293-300 (1984)

Young, "Bacteriophage Lysis: Mechanism and Regulation", Microbiol. Rev., 56:430-481

Applicants do not intend to represent that any of the documents listed herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicants respectfully request that this list of documents herein be considered and made of record in this application.

Respectfully submitted,



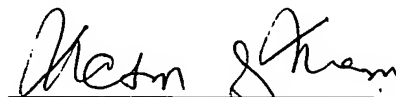
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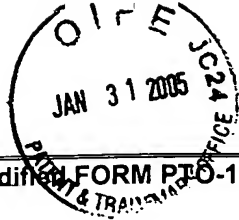
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January 28, 2005

Date



Nasim G. Memon



Modified FORM PTO-1449 & TRANSMITTAL	ATTY. DOCKET NO. MEG-207.1 US-1	SERIAL NO. 10/620,777
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT Roy CURTISS III	
Sheet 1 of 6	FILING DATE July 15, 2003	GROUP 1645

REFERENCE DESIGNATION

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,190,495	2/26/80	Curtiss			
	AB	4,968,619	11/6/90	Curtiss			
	AC	5,190,931	3/2/93	Inouye			
	AD	5,681,745	10/28/97	Szafranski, et al.			
	AE	5,702,916	12/30/97	Molin, et al.			
	AF						

FOREIGN PATENT DOCUMENTS

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	AG	EP 0381706 B1	4/26/1995	Curtiss				
	AH							

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AI	Barrett, <u>Textbook of Immunology</u> , Fourth Edition, (C. V. Mosby Co., St. Louis, MO, 1983)
	AJ	Bienkowska-Szewczyk et al., "The R Gene Product of Bacteriophage λ ", <u>Mol. Gen Genet.</u> , 184:111-114 (1981)
	AK	Bochner et al., "Positive Selection for Loss of Tetracycline Resistance", <u>J. Bacteriol.</u> , 143:926 (1980)
	AL	Brosius, "Plasmid Vectors for the Selection of Promoters", <u>Gene</u> , 27:151-160 (1984)
	AM	Cardenas and Clements, "Oral Immunization Using Live Attenuated <i>Salmonella</i> spp. as Carriers of Foreign Antigens", <u>Clinical Micro. Rev.</u> , 5(3) :328-342 (1992)
	AN	Cardineau and Curtiss, "Nucleotide Sequence of the <i>asd</i> Gene of <i>Streptococcus mutans</i> ", <u>J. Bio. Chem.</u> , 262:3344-3353 (1987)
	AO	Chatfield et al., "Construction of a Genetically Defined <i>Salmonella typhi</i> Mutant for the Engineering of a Candidate Oral Typhoid-Tetanus Vaccine", <u>Vaccine</u> , 10:53-60 (1992)
	AP	Chatfield et al., "The Development of Oral Vaccines Based on Live Attenuated <i>Salmonella</i> Strains", <u>FEMS Immunol. Med. Microbiol.</u> , 7:1-7 (1993)
	AQ	Christie, et al., "Synthetic Sites for Transcription Termination and a Functional Comparison with Tryptophan Operon Termination Sites <i>In Vitro</i> ", <u>Proc. Natl. Acad. Sci. USA</u> , 78:4180-4184 (1981)

AR	Clements, "Use of Attenuated Mutants of <i>Salmonella</i> as Carriers for Delivery of Heterologous Antigens to the Secretary Immune System", <u>Pathol. Immunopathol. Res.</u> , 6:137-146 (1987)
AS	Cornelis, "Yersiniae, Finely Tuned Pathogens", <u>Molecular Biology of Bacterial Infections</u> (Cambridge University Press, Cambridge, 1992)
AT	Curtiss, III. "The Release of Genetically-Engineered Microorganisms", <u>Proceedings of the First International Conference on the Release of Genetically-Engineered Microorganisms</u> (Sussman et al. editors., Academic Press, pp. 7-19, 1988.
AU	Curtiss, "Genetic Manipulation of Microorganisms: Potential Benefits and Biohazards", <u>Ann. Rev.</u> , 30:507-533 (1976)
AV	Curtiss et al., "Research on Bacterial Conjugation with Mini-Cells and Minicell-Producing <i>E. Coli</i> Strains", <u>Microbial Drug Resistance</u> , 3:169-183 (1982)
AW	Curtiss and Kelly, " <i>Salmonella Typhimurium</i> Deletion Mutants Lacking Adenylate Cyclase and Cyclic AMP Receptor Protein are Avirulent and Immunogenic", <u>Infect. Imm.</u> , 55:3035-3043 (1987)
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AY	Curtiss et al., "Avirulent <i>Salmonella</i> Expressing Virulence Antigens from other Pathogens for Use as Orally Administered Vaccines", <u>Virulence Mechanisms Of Bacterial Pathogens</u> (Roth, American Society for Microbiology, Washington, D.C., 1988) pages 311-328
AZ	Curtiss et al., "Recombinant <i>Salmonella</i> Vectors in Vaccine Development", <u>Dev. Biol. Stand.</u> , 82:23-33 (1994)
BA	Curtiss et al., "Stable Recombinant Avirulent <i>Salmonella</i> Vaccine Strains", <u>Adv. E. Med. Biol.</u> , 251:33-47 (1989)
BB	Curtiss et al., "Selective Delivery of Antigens by Recombinant Bacteria", <u>Curr. Topics Micro. Immun.</u> , 46:35-49 (1989)
BC	Curtiss, "Attenuated <i>Salmonella</i> Strains as Live Vectors for the Expression of Foreign Antigens", <u>New Generation Vaccines</u> (Woodrow and Levine, eds., Marcel Dekker, New York, 1990) pages 161-188
BD	Doggett and Curtiss, "Delivery of Antigens by Recombinant Avirulent <i>Salmonella</i> Strains", <u>Adv. Exp. Med. Biol.</u> , 327:165-73 (1992)
BE	Dorman et al., "Characterization of Porin and ompR Mutants of a Virulent Strain of <i>Salmonella typhimurium</i> : ompR Mutants are Attenuated <i>In Vivo</i> ", <u>Infect. Immun.</u> , 57:2136-40 (1989)
BF	Dougan et al., "Live Oral Salmonella Vaccines: Potential Use of Attenuated Strains as Carriers of Heterologous Antigens to the Immune System", <u>Parasite Immun.</u> , 9:151-160 (1987)
BG	Dul et al., "Genetic Mapping of a Mutant Defective in D, L-Alanine Racemase in <i>Bacillus Subtilis</i> 168", <u>J. Bacteriol.</u> , 115:1212 (1973)
BH	Ferrari et al., "Isolation of an Alanine Racemase Gene from <i>Bacillus Subtilis</i> and its Use for Plasmid Maintenance in <i>B. Subtilis</i> ", <u>Bio/Technology</u> , 3:1003-1007 (1985)
BI	Gait, ed., "Oligonucleotide Synthesis", <u>A Practical Approach</u> , (1984)
BJ	Galan and Curtiss, "Virulence and Vaccine Potential of phoP Mutants of <i>Salmonella typhimurium</i> ", <u>Microb. Pathogen.</u> , 6:433-443 (1989)

BK	Galan et al., "Cloning and Characterization of the <i>asd</i> gene of <i>Salmonella typhimurium</i> : Use in Stable Maintenance of Recombinant Plasmids in Salmonella Vaccine Strains", <u>Gene</u> , 94(1):29-35 (1990)
BL	Gentshev et al., " <i>Salmonella</i> Strain Secreting Active Listeriolysin Changes its Intracellular Localization", <u>Infect. Imm.</u> , 63(10) :4202-4205 (1995)
BM	Gerdes et al., "Mechanism of Postsegregational Killing by the <i>hok</i> Gene Product of the <i>parB</i> System Of Plasmid R1 and its Homology with the <i>relF</i> Gene Product of the <i>E. coli relB</i> Operon", <u>EMBO J.</u> , 5:2023-2029 (1986)
BN	Gerdes et al., "The <i>hok</i> Killer Gene Family in Gram-Negative Bacteria", <u>New Biol.</u> , 2:946-956 (1990)
BO	Gerdes et al., "Unique Type of Plasmid Maintenance Function: Postsegregational Killing of Plasmid-Free Cells", <u>Proc. Nat'l Acad. Sci. USA</u> , 83:3116-3120 (1986)
BP	Germanier and Furer, "Immunity in Experimental Salmonellosis", <u>Infect. Immun.</u> , 4:663-73 (1971)
BQ	Germanier and Purer, "Isolation and Characterization of <i>Gal E</i> Mutant Ty 21a of <i>Salmonella typhi</i> : A Candidate Strain for a live, oral Typhoid vaccine", <u>J. Infect. Dis.</u> , 131:553-8 (1975)
BR	Giladi et al., "Integation Host Factor Stimulates the. Phage Lambda pL Promoter", <u>J. Mol. Biol.</u> , 231:109-121 (1990)
BS	Givskov et al., "Cloning and Expression in <i>Escherichia coli</i> of the Gene for extracellular Phospholipase A1 from <i>Serratia liquefaciens</i> ", <u>J. Bacteriol.</u> , 170:5855-5862 (1988)
BT	Glover, ed., "DNA Cloning", <u>A Practical Approach</u> , Volumes I and II (1985)
BU	Guzman et al., "Tight Regulation, Modulation, and High-Level Expression by Vectors containing the Arabinose PBAD Promoter", <u>J. Bacteriol.</u> , 177(14) :4121-4130 (1995)
BV	Hames and Higgins, eds., "Nucleic Acid Hybridization", <u>A Practical Approach</u> (1984)
BW	Hecker et al., "Role of <i>relA</i> Mutation in the Survival of Amino Acid-Starved <i>Escherichia coli</i> ", <u>Arch. Microbiol.</u> , 143:400-402 (1986)
BX	Helander et al., "Preferential Synthesis of Heptaacyl Lipopolysaccharide by the <i>ssc</i> Permeability Mutant Of <i>Salmonella typhiinurium</i> ", <u>Eur. J. Biochem.</u> , 204:1101-1106 (1992)
BY	Hess et al., "Superior efficacy of secreted over Somatic Antigen display in Recombinant Salmonella Vaccine induced Protection against Listeriosis", <u>Proc. Natl. Acad. Sci. USA</u> , 93:1458-1463 (1996)
BZ	Hirvas et al., "Identification and Sequence Analysis of the Gene Mutated in the Conditionally Lethal Outer Membrane Permeability Mutant SS-C Of <i>Salmonella typhimurium</i> ", <u>EMBO J.</u> , 10(4) :1017-1023 (1991)
CA	Hoe et al., "Temperature Sensing in <i>Yersinia pestis</i> : Regulation of <i>yopE</i> Transcription by <i>lcrF</i> ", <u>J. Bacteriol.</u> , 174:4275-4286 (1992)
CB	Hone et al., "A <i>galE</i> via (Vi Antigen-Negative) Mutant of <i>Salmonella typhi</i> Ty2 retains Virulence in Humans", <u>Infect. Immun.</u> , 56:1326-1333 (1988)
CC	Hromockyi et al., "Temperature Regulation of Shigella Virulence: Identification of the Repressor Gene <i>virR</i> , An Analogue of <i>hns</i> , and Partial Complementation by Tyrosyl transfer RNA (tRNA ^{Tyr})", <u>Mol. Micro.</u> , 6:2113-2124 (1991)
CD	Jagusztyn-Krynicka et al., "Expression of <i>Streptococcus mutans</i> Aspartate-Semialdehyde Dehydrogenase gene cloned into plasmid pBR322", <u>J. Gen. Microbiol.</u> , 128:1135-1145 (1982)

CE	Johnson et al., "The Role of s Stress-Response Protein in <i>Salmonella typhimurium</i> Virulence", <u>Mol. Microbiol.</u> , 5:401-407 (1991)
CF	Jones et al., "Induction Of Proteins In Response To Low Temperature In <i>Escherichia coli</i> ", <u>J. Bacteriol.</u> , 169:2092-2095 (1987)
CG	Kaniga et al., "A Wide-Host Suicide Vector For Improving Reverse Genetics In Gram-Negative Bacteria: Inactivation Of The <i>blaA</i> Gene Of <i>Yersinia enterocolitica</i> ", <u>Gene</u> , 109:137-141 (1991)
CH	Kelly et al., "Characterization And Protective Properties Of Attenuated Mutants Of <i>Salmonella choleraesuis</i> ", <u>Infect. Immun.</u> , 60:4881-4890 (1992)
CI	Kingsbury et al., "Temperature-Sensitive Mutants for the Replication of Plasmids in <i>Escherichia coli</i> : Requirement for Deoxyribonucleic Acid Polymerase I in the Replication of the Plasmid ColE1", <u>J. Bacteriol.</u> , 114:1116-1124 (1973)
CJ	Knudsen and Karlstrom, "Development of Efficient Suicide Mechanisms for Biological Containment of Bacteria", <u>Applied and Environmental Microbiology</u> , 57(1) :85-92 (1991)
CK	Kushner, "Construction of Versatile Low-Copy-Number Vectors for Cloning, Sequencing and Gene Expression in <i>Escherichia coli</i> ", <u>Gene</u> , 100:195-199 (1990)
CL	Lambert de Rouvroit et al., "Role of the Transcriptional Activator, VirF, and Temperature in the Expression of the pYV Plasmid Genes of <i>Yersinia enterocolitica</i> ", <u>Molec. Microbiol.</u> , 6:395-409 (1992)
CM	Lieb, "Studies of Heat-Inducible Lambda Bacteriophage", <u>J. Mol. Biol.</u> , 16:149-163 (1966)
CN	Lugtenberg et al., "Temperature-Sensitive Mutant of <i>Escherichia coli</i> K-12 with an Impaired D-Alanine: D-Alanine Ligase", <u>J. Bacteriol.</u> , 113:96-104 (1973)
CO	McGhee and Mestecky, "The Secretory Immune System", <u>Ann. N.Y. Acad. Sci.</u> , Volume 409 (1983)
CP	Miller, <u>Experiments In Molecular Genetics</u> (Cold Spring Harbor Laboratory, 1972)
CQ	Miller et al., "A two-component regulatory system (phoP phoQ) controls <i>Salmonella typhimurium</i> virulence", <u>Proc. Natl. Acad. Sci. USA</u> , 86:5054-5058 (1989)
CR	Miller and Mekalanos, "A Novel Suicide Vector and its Use in Construction of Insertion Mutations: Osmoregulation of Outer Membrane Proteins and Virulence Determinants in <i>Vibrio cholerae</i> requires <i>toxR</i> ", <u>J. Bacteriol.</u> , 170:2575-2583 (1988)
CS	Miller, <u>A Short Course In Bacterial Genetics</u> (Cold Spring Harbor Laboratory, 1992)
CT	Miyakawa et al., "Cell Wall Peptidoglycan Mutants of <i>Escherichia coli</i> K-12: Existence of Two Clusters of Genes, <i>mra</i> And <i>mrh</i> , For Cell Wall Peptidoglycan Biosynthesis", <u>J. Bacteriol.</u> , 112:950 (1972)
CU	Molin et al., "Suicidal Genetic Elements and their Use in Biological Containment of Bacteria", <u>Annual Review of Microbiology</u> , 47:139-166 (1993)
CV	Molin and Kjelleberg, "Release of Engineered Microorganisms: Biological Containment and Improved Predictability for Risk Assessment", <u>AMBIO</u> , 22{4} :242-245 (1993)
CW	Molin et al., "Conditional Suicide System for Containment of Bacteria and Plasmids", <u>Bio/Technology</u> , 5:1315-1318 (1987)
CX	Munthali et al., "Use of Colicin E3 for Biological Containment of Microorganisms", <u>App. Environ. Microbiol.</u> , 62{5} :1805-1807 (1996)

CY	Nakayama et al., "Construction of an ASD+ Expression-Cloning Vector: Stable Maintenance and High Level Expression of Cloned Genes in a Salmonella Vaccine Strain", <u>Bio/Technology</u> , 6:693-697 (1988)
CZ	Neidhardt et al., "The Genetics and Regulation of Heat-Shock Proteins", <u>Annu. Rev. Genet.</u> , 18:295-329 (1984)
DA	Nystrom, "Role Of Guanosine Tetraphosphate in Gene Expression and the Survival of Glucose or Seryl-tRNA Starved Cells of <i>Escherichia coli</i> K12", <u>Mol. Gen. Genet.</u> , 245:355-362 (1994)
DB	O'Brien, ed., <u>Genetic Maps</u> (Cold Spring Harbor Laboratory, 1987)
DC	O'Connor and Timmis, "Highly Repressible Expression System for Cloning Genes that Specify Potentially Toxic Proteins", <u>J. Bacteriol.</u> , 169:4457-4462 (1987)
DD	Orga et al., <u>Handbook of Mucosal Immunology</u> (Academic Press, San Diego, CA, 1994)
DE	Perbal, <u>A Practical Guide To Molecular Cloning</u> , A Wiley- Interscience Publication (1984)
DF	Poteete et al., "Operator Sequences of Bacteriophages P22 And 21", <u>J. Mol. Biol.</u> , 137:81-91 (1980)
DG	Poulsen et al., "The <i>gef</i> Gene from <i>Escherichia coli</i> is Regulated at the Level of Translation", <u>Mol. Microbiol.</u> , 5:1639-1648 (1991)
DH	Qoronfleh et al., "Identification and Characterization of Novel Low-Temperature-Inducible Promoters of <i>Escherichia coli</i> ", <u>J. Bacteriol.</u> , 174:7902-7909 (1992)
DI	Ramos et al., "Suicide Microbes on the Loose", <u>Bio/Technology</u> , 13:35-37 (1995)
DJ	Reader and Siminovitch, "Lysis Defective Mutants of Bacteriophage Lambda: On the Role of the S Function in Lysis ¹ ", <u>Virology</u> , 43:623-637 (1971)
DK	Reddy, et al., "Hyperexpression and Purification of <i>Escherichia Coli</i> Adenylate Cyclase Using a Vector Designed for Expression of Lethal Gene Products", <u>Nucleic Acids Res.</u> , 17(24) :10473-10489 (1989)
DL	Remaut, et al., "Plasmid Vectors for High-Efficiency Expression controlled by the pL Promoter of Coliphage Lambda", <u>Gene</u> , 15:81-93 (1981)
DM	Remaut, et al., "Improved Plasmid Vectors with a Thermoinducible Expression and Temperature-Regulated Runaway Replication", <u>Gene</u> , 22:103-113 (1983)
DN	Rennell and Poteete, "Phage P22 Lysis Genes: Nucleotide Sequences and Functional Relationships with T4 and λ Genes", <u>Virology</u> , 143:280-289 (1985)
DO	Rodriguez and Denhardt, eds., <u>Vectors: A Survey Of Molecular Cloning Vectors And Their Uses</u> (Butterworths, 1987)
DP	Sambrook et al., <u>Molecular Cloning: A Laboratory Manual</u> (Cold Spring Harbor Laboratory, 1989)
DQ	Sanger et al., "Nucleotide Sequence of Bacteriophage λ DNA", <u>J. Mol. Biol.</u> , 162:729-773 (1982)
DR	Sauer et al., "Primary Structure of the Phage P22 Repressor and its Gene <i>c2</i> ", <u>Biochem.</u> , 20:3591-3598 (1981)
DS	Schadel, "Oral Vaccination using Recombinant Bacteria", <u>Semin. Immunol.</u> , 2:341-349 (1990)
DT	Schadel, "Recombinant Avirulent Salmonellae as Oral Vaccine Carriers", <u>Infection</u> , 20(1):1-8 (1992)

	DU	Schweder et al., " <i>Escherichia coli</i> K12 relA Strains as safe Hosts for Expression of Recombinant DNA", <u>Appl. Microbiol. Biotechnol.</u> , 42:718-723 (1995)
	DV	Sigwart et al., "Effect of a purA Mutation on Efficacy of Salmonella Live-Vaccine Vectors", <u>Infection and Immunity</u> , 57(6) :1858-1861 (1989)
	DW	Sites et al., <u>Basic and Clinical Immunology</u> (Lange Medical Books, Los Altos, CA, 1994)
	DX	Sizemore et al., "Attenuated <i>Shigella</i> as a DNA Delivery Vehicle for DNA-Mediated Immunization", <u>Science</u> , 270:299-302 (1995)
	DY	Spector and Cubitt, "Starvation-Inducible Ioci of <i>Salmonella typhimurium</i> : Regulation and Roles in Starvation-Survival", <u>Mol. Micro.</u> , 6:1467-1476 (1992)
	DZ	Studier et al., "Gene Expression Technology", <u>Methods Enzymol.</u> , 185:60-89 (1990)
	EA	Tacket et al., "Comparison of the Safety and Immunogenicity of Acya ACrp <i>Salmonella typhi</i> Strains in Adult Volunteers", <u>Infect. Immun.</u> , 60:536-541 (1992)
	EB	Tanabe et al., "Identification of the Promoter Region of the <i>Escherichia coli</i> Major Cold Shock Gene, <i>cspA</i> ", <u>J. Bacteriol.</u> 174:3867-3873 (1992)
	EC	Tao and Blumenthal, "Sequence and Characterization of pvuIIR, The PvuII Endonuclease Gene, and of puvIIC, Its Regulatory Gene", <u>J. Bacteriol.</u> , 174(10) :3395-3398 (1992)
	ED	Temple et al., "Survival of two <i>Enterobacteria</i> in feces buried in soil under field conditions", <u>Appl. Environ. Microbiol.</u> , 40:794-797 (1980)
	EE	Tobe et al., "Temperature-Regulated Expression of Invasion Genes in <i>Shigella Flexneri</i> is Controlled through the Transcriptional Activation of the virB Gene on the large Plasmid", <u>Mol. Micro.</u> 5:887-893 (1991)
	EF	Umbarger, "Amino Acid Biosynthesis and its Regulation", <u>Ann. Rev. Biochem.</u> , 47:533 (1978)
	EG	Vasina and Baneyx, "Recombinant Protein Expression at Low Temperatures under the Transcriptional Control of the Major <i>Escherichia coli</i> Cold Shock Promoter <i>cspA</i> ", <u>Appl. Environ. Micro.</u> 62(4) :1444-1447 (1996)
	EH	Vuorio and Vaara, "Mutants carrying conditionally lethal Mutations in Outer Membrane Genes <i>omsA</i> And <i>lirA</i> (<i>ssc</i>) are Phenotypically similar, and <i>omsA</i> is Allelic to <i>firA</i> ", <u>J. Bacteriol.</u> , 174(22) :7090-7097 (1992)
	EI	Wijsman, "The characterization of an Alanine Racemase mutant of <i>Escherichia coli</i> ", <u>Genet. Res. Camb.</u> , 20:269-277 (1972)
	EJ	Wijsman, "A Genetic Map of several mutations affecting the Mucopeptide layer of <i>Escherichia coli</i> ", <u>Genet. Res. Camb.</u> , 20:65- 74 (1972)
	EK	Yarrington et al., "Dual-Origin Plasmid Vectors whose Origin of Replication is Controlled by the Coliphage Lambda Promoters PL", <u>Gene</u> , 28:293-300 (1984)
	EL	Young, "Bacteriophage Lysis: Mechanism and Regulation", <u>Microbiol. Rev.</u> , 56:430-481 (1992)
EXAMINER		DATE CONSIDERED

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